

### **REMARKS**

Claims 36, 38, 41-44, 46, and 48 remain in the present application. Claims 1-35, 37, 40, and 47 have been previously canceled. Claims 39 and 45 are canceled. No additional claims fee is believed to be due.

Claims 36 and 43 have been amended to incorporate the mean particle size property of the claimed silicon dioxide component. Support for these amendments is found in canceled Claims 39 and 45.

### **Invention Synopsis**

The present invention is directed to oral, liquid, aqueous, muco-retentive compositions, and a method of administering such compositions, wherein the compositions comprise colloidal particles of select silicon dioxide, a select pharmaceutical active, and a citric acid.

It has been found that prolonged and improved coating and protection of components of the alimentary canal such as the stomach, esophagus, and small intestine can be achieved by incorporating a mucoadhesive material into an oral pharmaceutical composition. Unlike conventional mucoadhesive materials such as mucoadhesive polymers, the compositions of the present invention comprise a silicon dioxide which provides for highly effective mucoadhesive systems. It has also been found that when the compositions of the present invention comprise a citric acid, the solid particles of these highly effective mucoadhesive systems are consistently dispersed to result in improved stability of the systems.

### **Formal Matters**

Claims 36, 38-39, 41-46, and 48 have been rejected under the judicially created doctrine of non-statutory double patenting over Claims 1-13 of Application Serial No. 10/021,327, now U.S. Patent No. 6,638,521. The Examiner contends that Applicant's Claims 36, 38-39, 41-46, and 48 are similar in scope as compared to the subject matter of Claims 1-13 of U.S. Patent No. 6,638,521, wherein Applicant's Claims 36, 38-39, 41-46, and 48 relate to oral, liquid, aqueous, muco-retentive compositions, and a method of administering such compositions, wherein the compositions comprise colloidal particles of silicon dioxide, a select pharmaceutical active, and a citric acid. Responsive to this rejection, Applicant submits a terminal disclaimer, thus obviating this rejection.

### **Art Rejection**

Claims 36, 38-39, 41-46, and 48 have been rejected under 35 U.S.C. 103 as being unpatentably obvious over Rice (U.S. Patent 5,589,160) or Rice (U.S. Patent 5,658,533). The Examiner contends that it would have been obvious to realize Applicant's invention based on the Rice disclosures of pharmaceutical formulations comprising precipitated silica, a sensory agent, and other pharmaceutical excipients such as surfactants and citric acid. Applicant submits that Claims 39 and 45 have been canceled without prejudice, thus obviating this rejection as it would apply to these claims. Applicant

respectfully traverses this rejection as it would apply to remaining amended Claims 36, 38, 41-44, 46, and 48.

Rice, the '160 Patent, and Rice, the '533 Patent, disclose oral compositions such as oral gels, toothpastes, tooth powders, prophylaxis pastes, lozenges, and gums wherein the oral compositions comprise a select precipitated silica. The Rice documents further disclose that the oral compositions can comprise other ingredients such as a surfactant, a chelating agent such as citric acid, and flavoring agents including oil of clove. The Rice documents, however, fail to disclose an oral, mucoretentive, aqueous liquid, pharmaceutical composition that comprises colloidal particles of silicon dioxide wherein the silicon dioxide has a mean particle size of less than about 1 micron.

Applicant submits that the Rice references would not obviously lead the skilled artisan to a realization of Applicant's invention of remaining Claims 36, 38, 41-44, 46, and 48, as amended. The Rice references are directed to dentifrice compositions that comprise precipitated silica having a mean particle size of from about 5 to about 11 microns. By contrast, Applicant's amended Claims 36, 38, 41-44, 46, and 48 are now limited to an oral, mucoretentive, aqueous liquid, pharmaceutical composition comprising colloidal particles of silicon dioxide having a mean particle size of less than about 1 micron.

Moreover, Applicant submits that the Rice references are completely silent to the teaching or suggestion of *mucoretentive* pharmaceutical compositions. The applied Rice references teach and suggest dentifrice compositions that provide improved dental cleaning with minimal abrasion, and these particularly applied references fail to mention altogether any *mucoretentive* properties achieved by the Rice dentifrice compositions. At minimal, the applied Rice references should teach or suggest *mucoretentive* pharmaceutical compositions. The Examiner contends that "The composition of '160 and '553 is used for preventing tooth stain or removing plaque and applied as toothpaste, thus meets the claimed limitation limitations "oral, mucoretentive"". Applicant disagrees, and submits that in order to obviously lead the skilled artisan to a realization of Applicant's invention the applied Rice references should teach or suggest the compositions as claimed by Applicant, and both of the applied Rice references fail to teach or suggest *mucoretentive* pharmaceutical compositions.

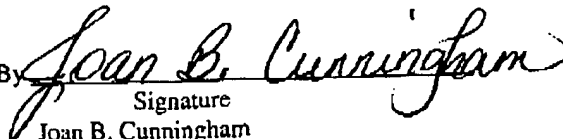
In view of the foregoing remarks, it is submitted that the Rice references fail to teach or suggest an oral, mucoretentive, aqueous liquid, pharmaceutical composition as now recited in Applicant's Claims 36, 38, 41-44, 46, and 48. Rejection of these claims, as amended, as being unpatentably obvious over the Rice references is improper and, therefore, should be withdrawn.

### Conclusions

Applicant has made an earnest effort to place his application in proper form and to distinguish his claimed invention from the applied prior art. WHEREFORE, reconsideration of this application, withdrawal of the double patenting rejection and rejection under 35 U.S.C. 103, and allowance of Claims 36, 38, 41-44, 46, and 48 are respectfully requested.

Respectfully submitted,

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